

REMARKS

I. STATUS OF CLAIMS

Claims 1-43 are pending in this application. Independent claims 1, 38, and 39 are amended herein. Support for these amendments can be found in the specification at least in paragraphs [020] and [031]. Accordingly, no new matter is added by these amendments.

II. REJECTION UNDER 35 U.S.C. § 103

A. Zawistowski

The Office rejected claims 1-24 and 32-43 under 35 U.S.C. § 103(a) as unpatentable over WO 00/45648 to Zawistowski ("Zawistowski"). Office Action at page 2. In response to Applicants arguments, the Office contends that there is no difference seen between the homogenization of Zawistowski and the homogenization recited in the pending claims. *Id.* Applicants continue to respectfully disagree for the reasons of record and additionally, for the reasons provided below.

Zawistowski describes the process of reducing phytosterol particle size comprising the steps of:

A. dispersing or otherwise suspending phytosterol in a suitable semi-fluid, fluid, or viscous vehicle, said vehicle being one in which phytosterols and phytostanols are not substantially soluble; and then

B. substantially reducing the particle size of the phytosterols and phytostanols by exposing the vehicle so formed to *impact forces* to produce microparticles.

Zawistowski at [0018] to [0020] (emphasis added). The reference to “impact forces” includes those forces “created by high-shear using either an air-atomization nozzle, a pneumatic nozzle, a high shear mixer or colloid mill or in a microfluidizer.” *Id.* at [0021]. In fact, Zawistowski teaches that “homogenizer valves . . . are [] fraught with limitations including the requirement for a high volume through put and low pressures (leading to variable particle size in end product).” *Id.* at [0024]. Zawistowski further teaches that “microfluidization, or particle collision technology, achieves what traditional homogenizers, . . . have failed to do” *Id.* at [0023]. At least by those express statements, Zawistowski teaches away from the use of homogenizers.

In contrast to Zawistowski’s teaching, the present invention discloses mixing and then homogenizing a dispersion of the at least one hydrophobic plant sterol and the aqueous material. With Zawistowski’s express assertion that “homogenizer valves . . . are also fraught with limitations” and that “impact forces” encompass “high shear using either an air-atomization nozzle, a pneumatic nozzle, a high shear mixer or colloid mill or in a microfluidizer,” Zawistowski fails to teach the step of “homogenizing the first dispersion to obtain” as recited in the present claims. As provided in the M.P.E.P., “[a] prior art reference that ‘teaches away’ from the claimed invention is a significant factor to be considered in determining obviousness” M.P.E.P. § 2145 (X)(D)(1).

Accordingly, without teaching all the claim limitations, a *prima facie* case of obviousness is not established. Applicants respectfully request the withdrawal of this rejection.

B. Yoon

The Office also rejected claims 1-43 under 35 U.S.C. § 103 as unpatentable over U.S. Patent Application Publication No. 2002/0064548 to Yoon ("Yoon"). Office Action at page 4. In response to Applicants' arguments, the Office contends that the claims are open to intermediate steps and that mere argument that applicants' invention is different from Yoon is not sufficient to overcome obviousness. *Id.* at page 5. Applicants continue to respectfully disagree for the reasons of record and additionally, for the reasons provided below.

In order to establish a *prima facie* case of obviousness, the cited references, *inter alia*, must teach or suggest all the claim elements. M.P.E.P. § 2143 (8th ed., Rev. 3, 2005). Here, like Zawistowski, Yoon fails to teach all the claim limitations.

Namely, Yoon utilizes emulsifiers in order to facilitate the preparation of nano-sized micelles. In particular, Yoon is directed to "a method of dispensing plant sterols into *micelles* with a size of hundreds of nanometers, which improves the bioavailability of sparingly soluble plant sterols, has proper dose proportionality, and shows a maximum of dispersion stability." *Id.* at [0032] (emphasis added). To produce such micelles, Yoon teaches:

1. admixing plant sterol with an *emulsifier*;
2. melting the admixture by heating at 60 - 200°C;
3. mixing the molten substance with an aqueous beverage; and
4. stirring the mixture at high speed to give a dispersion of plant sterols.

Id. at [0033] (emphasis added).

After “intensive research,” Yoon discovered that to produce micelle particles with a size of hundreds of nanometers or less, one needs to homogenously mix the plant sterol with an *emulsifier* by heating the plant sterol near its melting point “to bring the two components into liquid phases before mixing.” *Id.* at [0040]. It is only after those steps that the mixture is introduced into “an aqueous beverage or an emulsifier-containing aqueous beverage” that is in contact with a water based liquid. *Id.* at [0041]. Thus, the use of emulsifiers is at the core of Yoon’s invention.

In contrast, the amended independent claims recite that “the first and/or second dispersion do not use emulsifiers, thickening agents, and/or manufacturing aids to achieve the substantially stable dispersion of the at least one hydrophobic plant sterol in said aqueous material.” As detailed above, Yoon clearly teaches just the opposite, i.e., using such an emulsifier to obtain a stable dispersion of plant sterols. By doing so, Yoon teaches away from the present invention. In fact, “a prior art reference that ‘teaches away’ from the claimed invention is a *significant factor* to be considered in determining obviousness.” M.P.E.P. § 2145(X)(D)(1) (emphasis added).

Accordingly, without such teachings in Yoon, the Office fails to establish a *prima facie* case of obviousness. Applicants thus respectfully request the withdrawal of this rejection.

III. CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that this claimed invention, as amended, is not rendered obvious in view of the prior art references cited against this application. Applicants, therefore, request the entry of this


Amendment, the Examiner's reconsideration of the application, and the timely allowance of the pending claims. Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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